Application or Docket Number PATENT APPLICATION FEE DETERMINATION RECORD Effective January 1, 2003 **CLAIMS AS FILED - PART I SMALL ENTITY** OTHER THAN (Column 1) (Column 2) TYPE [OR SMALL ENTITY **TOTAL CLAIMS** RATE FEE RATE FEE FOR NUMBER FILED **NUMBER EXTRA** BASIC FEE 375.00 BASIC FEE 750.00 OR TOTAL CHARGEABLE CLAIMS minus 20= X\$ 9= X\$18= OR INDEPENDENT CLAIMS minus 3 = X42= X84= OR MULTIPLE DEPENDENT CLAIM PRESENT X +140= +280= OR * If the difference in column 1 is less than zero, enter "0" in column 2 TOTAL OR TOTAL **CLAIMS AS AMENDED - PART II** OTHER THAN SMALL ENTITY OR SMALL ENTITY (Column 1) (Column 3) (Column 2) CLAIMS HIGHEST 4 ADDI-ADDI-REMAINING NUMBER PRESENT **AMENDMENT** RATE TIONAL **AFTER PREVIOUSLY** RATE TIONAL **EXTRA AMENDMENT** PAID FOR FEE FEE Total 65 Minus X\$18= X\$ 8= OR 200 Independent Minus *** X42= X84 =OR FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM +140= +280= OR TOTAL TOTAL 200 OR ADDIT, FEE ADDIT. FEE (Column 1) (Column 2) (Column 3) CLAIMS HIGHEST ADDI-REMAINING NUMBER ADDI-PRESENT AMENDMENT **AFTER** TIONAL **PREVIOUSLY** RATE RATE **EXTRA** TIONAL AMENDMENT **PAID FOR** FEE FEE Total Minus X\$ 9= X\$18= OR Independent Minus *** X42= X84= FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM OR +140= +280= TOTAL TOTAL OR ADDIT. FEE ADDIT. FEE (Column 1) (Column 2) (Column 3) CLAIMS HIGHEST ပ REMAINING ADDI-NUMBER ADDI-PRESENT **AMENDMENT** AFTER PREVIOUSLY RATE TIONAL **EXTRA** RATE TIONAL AMENDMENT PAID FOR FEE FEE **Total** Minus X\$ 9= X\$18= OR Independent Minus X42 =X84= FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM OR +140= +280= OR * If the entry in column 1 is less than the entry in column 2, write "0" in column 3. TOTAL ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20." TOTAL ADDIT, FEE *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3." ADDIT. FEE The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

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Attorney Docket: 01662/60903

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:

Dolitzky et al.

Serial No.:

10/649,399

Filing Date:

August 26, 2003

Art Unit :1624

Examiner: Mark L. Berch

For: CRYSTALLINE SOLID FAMCICLOVIR FORMS I, II, III AND PREPARATION

THEREOF

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION

SIR:

Applicants petition for a three-month extension of time for responding to the Office Action dated August 30, 2005, wherein the petition fee can be charged to Deposit Account No. 11-0600. In response to the Office Action, applicants request that the application be amended as shown below.

Claim Amendments begin on page 2.

Remarks begin on page 8.

WO 2000/06573 does not disclose crystalline famciclovir form I or II. The Office Action asserts that WO 2000/06573 discloses triturating famciclovir with diethyl ether in Synthesis Example 11. However, Synthesis Example 11 of WO 2000/06573 merely discloses that a white powder was isolated after the elaboration, with diethyl ether, of a mixture containing crude anhydrous famciclovir (page 16, lines 7-9; emphasis added). WO 2000/06573 does not disclose trituration of anhydrous famciclovir with diethyl ether because elaboration does not mean trituration. WO 2000/06573 does not anticipate claim 18 because WO 2000/06573 does not disclose triturating anhydrous famciclovir in diethyl ether, isopropanol or acetonitrile. Following the process in WO 2000/06573 would not necessarily result in crystalline famciclovir form I containing less than 5% of another form of crystalline famciclovir, or crystalline famciclovir form II containing less than 5% of another form of crystalline famciclovir. Withdrawal of the anticipatory rejection of claims 1-10, 18, 19 and 31 over WO 2000/06573 is requested.

Page 3 of the Office Action indicates that Brand et al, *Tetrahedron* (1999) 55: 5239-5252, used aqueous acetone to crystallize famciclovir (page 5251, line 1). But page 2 of the Office Action does not reject any claims over Brand et al. Applicants request that the next Office Action explains which claim, if any, is rejected over Brand et al, so that applicants can respond.

Page 4 of the Office Action comments that, concerning claims 37-43, the crystalline form will dissolve if the excipient is water. Applicants note that claims 37-43 have been amended to direct to solid pharmaceutical compositions. Thus, the form of the compositions as claimed are not dissolved in water. Withdrawal of the rejection of claims 37-43 is requested.

In the event that the filing of this paper is deemed not timely, applicants petition for an appropriate extension of time. The petition fee and any other fees that may be required in relation to this paper can be charged to Deposit Account No. 11-0600 referencing Attorney Docket No. 01662/60903.

Respectfully submitted,

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Dated: February 28, 2006

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